

REMARKS

Applicants have carefully studied the Office Action mailed on December 5, 2001, which issued in connection with the above-identified application. The present response is intended to be fully responsive to all points raised by the Examiner. Favorable reconsideration and an early action on the merits is respectfully requested.

Claims 1-37 are pending and at issue in this application.

In the Action, the Examiner required restriction to one of the following Groups of claims under 35 U.S.C. § 121:

Group I: Claims 1-16, drawn to a method for transducing stem cells (class 435, subclass 455).

Group II: Claims 17-20, drawn to a population of stem cells (class 435, subclass 325).

Group III: Claims 21-25, allegedly¹ drawn to a method of stem cell transplantation (class 424, subclass 93.1).

Group IV: Claims 26 and 27, drawn to a method of treating a disease or disorder (class 424, subclass 93.1).

Group V: Claims 28-30, drawn to a non-human animal engrafted with the stem cells (class 800,

¹ It is respectfully brought to the Examiner's attention that claims 21-25 are drawn to a method for introducing a gene of interest into a host.

subclass 8).

Group VI: Claims 31-37, drawn to a kit and a method for preparing said kit (class 435, subclass 320.1).

In the Office Action, the Examiner contends that the inventions are distinct because allegedly (i) inventions of Groups I and II , I and V, I and VI, II and III, II and IV, IV and VI are drawn to materially different compositions and methods that require different starting materials and modes of operation; (ii) the inventions of Groups I and III, I and IV, II and IV are drawn to methods that require different starting materials and modes of operation; ; (iii) the inventions of Groups II and V are drawn to materially distinct compositions that are not directly related, and (iv) the inventions of Groups II and VI, III and V, III and VI, IV and V, V and VI are drawn to materially distinct compositions and methods that are not directly related.

In order to be fully responsive to the Requirement for Restriction, applicants hereby elect, with traverse, to prosecute the claims of Group I (claims 1-16) directed to a method for transducing stem cells.

Although applicants are making the above election to be fully responsive to the Requirement for Restriction, applicants respectfully traverse the Requirement and reserve the right to petition therefrom under 37 C.F.R. § 1.144. In particular, applicants respectfully request reconsideration of the Restriction Requirement to allow prosecution of all pending claims in the same application, or, in the alternative, modification of the Requirement to allow prosecution of

more than one of the above groups, for the reasons provided as follows.

Under 35 U.S.C. § 121, "two or more independent and distinct inventions . . . in one application may . . . be restricted to one of the inventions". Inventions are "independent" if there is no distinct relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01, July 1988) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or,
3. Different field of the search.

Moreover, according to Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Applicants respectfully submit that Groups I-VI fail to define inventions that warrant separate examination and search. Indeed, claims of Groups I, II and VI are classified in the same search class (435), and claims of Groups II and IV are classified not only in the same search class (424) but also in the same subclass (93.1). Accordingly, searches of claims within these two groups will be coextensive. In addition, as provided below, the claims in Groups I-VI contain a number of

unifying features.

Thus, as correctly noted by the Examiner (at page 2 of the Office Action), the method recited in the claims of Group I is used to produce the stem cells recited in the claims of Group II. Applicants further respectfully submit that, in contrast to the Examiner's assertion, the generation of stem cells transduced with vector particles containing a gene of interest by co-culturing them with producer cells does not constitute an alternative method of production because producer cells generate vector particles, which then infect the stem cells. In other words, co-culturing with producer cells merely represents another way to do the same thing.

Applicants also respectfully note that the claims of Groups III, IV and V recite the use of the stem cells of claim 17 (Group II). Accordingly, the claims of Groups III, IV and V share patentability issues with the claims of Group II.

In light of the foregoing arguments, it can be concluded that the claims of provisionally elected Group I contain multiple unifying features with the claims of Groups II-VI, and, in particular, with the claims of Group II. Hence, it is believed that a single search of the features of the stem cell transduction method recited in the claims of Group I would necessarily and unescapably require a search of the subject matter of the claims of Group II, and will overlap with the search of the subject matter of Groups III-VI.

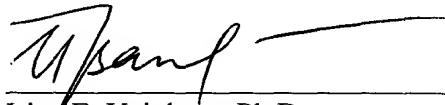
In closing, applicants respectfully submit that the groups of claims designated by the Examiner fail to define methods and compositions that warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. Thus, the search and examination of each group is necessarily co-extensive,

and in any event would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. Accordingly, applicants respectfully request that the Examiner withdraws the Requirement for Restriction and examines all of the pending claims in a single application or at least modifies the Requirement to allow prosecution of more than one of the above groups.

CONCLUSION

Applicants request entry of the foregoing remarks in the file history of this application. In view of the above arguments, withdrawal or modification of the Requirement for Restriction is respectfully requested, and an early action on the merits is courteously solicited.

Respectfully submitted,



Irina E. Vainberg, Ph.D.
Reg. No. 48,008
Agent for Applicants

DARBY & DARBY, P.C.
805 Third Avenue
New York, N.Y. 10022
Phone (212) 527-7700